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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/555,467	09/11/2006	**Cheung Hoi Yu**	2055.043	7542

23405 7590 03/16/2010

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	**PAPER NUMBER**
1637	
MAIL DATE	**DELIVERY MODE**
03/16/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/555,467	YU ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-19 and 26-41* is/are pending in the application.

4a) Of the above claim(s) *1,2,4,17-19 and 26-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 November 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/24/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 24, 2010 has been considered.

Status of the Application

2. The action is in response to the RCE filed on February 24, 2010. Currently claims 5-16 are pending under examination. Claims 3, 20-25 are cancelled. Claim 1-2, 4, 17-19, 26-41 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group. All arguments were fully considered and thoroughly reviewed and deemed persuasive.

Information Disclosure Statement

3. The Information Disclosure Statement filed on February 24, 2010 has been considered.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5-8, 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Ratge et al. (J Clin Virol., Vol. 24, pp. 161-172, April 2002).

Ratge et al. teach a method of claim 5, 10, for nucleic acid (RNA) detection comprising the steps of nucleic acid isolation of infectious agent, nucleic acid amplification of the pathogen and performing on the pathogenic nucleic acid of the infectious agent real time PCR (see page 163, section 2.1-2.3.2, page 164, col. 1 and 2 section 2.4, page 165, Fig.1).

With regard to claim 6, Ratge et al. teach that the nucleic acid amplification comprises PCR (see page 164, col. 1, paragraph 1-2 under section 2.4).

With regard to claim 7, Ratge et al. teach that said real time PCR uses fluorescently labeled probes (see page 164, col. 2, paragraph 1).

With regard to claim 8, Ratge et al. teach that the nucleic acid is cDNA (see page 164, col. 1, paragraph 1-2 under section 2.4).

With regard to claim 11, Ratge et al. teach that the method further comprises obtaining RNA from the biological sample and converting the RNA to cDNA using reverse transcriptase (see page 164, col. 1, paragraph 1-2 under section 2.4).

With regard to claim 12, Ratge et al. teach that the steps amplification and real time PCR uses primers (see page 164, col. 1, paragraph 1-2 under section 2.4, col. 2, paragraph 1).

Accordingly the claims are anticipated.

Response to Arguments:

5. With regard to the rejection of claims 5-6, 8-16 under 35 USC 102(e) as being anticipated by Peiris et al. (US 7,375,202) (hereafter Peiris I), Applicants' arguments were fully considered and found unpersuasive. Applicants argue that Peiris I does not teach pre-amplification prior to RT-PCR or real-time PCR. The arguments were found unpersuasive. First, the claims as presented do not recite pre-amplification, nor requires the PCR product from the first round PCR for

performing real-time PCR, because the claims recite 'amplifying the nucleic acid of the infectious agent and performing real time PCR on the nucleic acid of the pathogenic agent, which clearly indicate two separate PCR reactions that do not require the use of amplified nucleic acid from the first round PCR to perform real-time PCR. Second, Peiris I does teach two separate PCR reactions (RT-PCR and a real-time PCR) using the nucleic acid of the pathogenic agent. Third, the broader scope of the claims do not exclude amplification by RT-PCR and a second real-time PCR using the nucleic acid of the pathogenic agent. Accordingly the rejection is maintained.

6. With regard to the rejection of claims 5-16 under 35 USC 102(e) as being anticipated by Peiris et al. (US 7,267,942) (hereafter Peiris II), Applicants' arguments were fully considered and found unpersuasive. Applicants argue that Peiris II does not teach pre-amplification prior to RT-PCR or real-time PCR. The arguments were found unpersuasive. The claims as presented do not recite pre-amplification, nor requires the PCR product from the first round PCR for performing real-time PCR, because the claims recite 'amplifying the nucleic acid of the infectious agent and performing real time PCR on the nucleic acid of the pathogenic agent, which clearly indicate two separate PCR reactions that do not require the use of amplified nucleic acid from the first round PCR to perform real-time PCR. Second, Peiris II does teach two separate PCR reactions (RT-PCR and a real-time PCR) using the nucleic acid of the pathogenic agent. Third, the broader scope of the claims do not exclude amplification by RT-PCR and a second real-time PCR using the nucleic acid of the pathogenic agent. Accordingly the rejection is maintained.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suryaprabha Chunduru/

Primary Examiner, Art Unit 1637